DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9/852d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

October 12, 2001

Our Reference: 2937278

Su Wuan Lee Mai
Mese Hsin Tung Yang Foods, Inc.
Dba New Horizon Company
405 South Airport Blvd.
South San Francisco, CA 94080

WARNING LETTER

Dear Ms. Mai:

We inspected your seafood firm, New Horizon Company, 405 South Airport Blvd. South San Francisco, CA, on September 12 and 19, 2001. We conducted this inspection to determine your compliance with the Food and Drug Administration's (FDA) Fish and Fishery Product's regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123).

We found that your firm has serious Hazard Analysis and Critical Control Point (HACCP) deficiencies. These deficiencies cause your fish and fishery products, specifically roasted eel in soy sauce and ready-to-eat shredded squid, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that, the fish and fishery products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. We listed the HACCP deficiencies and Form FDA 483 and discussed them with Ms. Katherine M.Y. Wong, Associate Manager, at the conclusion of the inspection. We are enclosing a copy of the Form FDA 483 for your ready reference. Your serious HACCP violations are as follows:

1. You must have written product specifications that are designed to ensure that the fish and fishery products that you import are not injurious to health as required by 21 CFR 123.12(a)(2)(i). Our inspection found that you did not have written product specifications for roasted eel in soy sauce and ready-to-eat shredded squid.

2. You must implement an affirmative step that ensures that the fish and fishery products that you import are processed in accordance with the seafood HACCP regulation as required by 21 CFR 123.12(a)(2)(ii). Our inspection reveled that you did not perform an affirmative step for the roasted eel in soy sauce.

The above violations are not meant to be an all inclusive list of deficiencies at your firm. It is your responsibility to assure that all your products are in compliance with applicable laws and regulations enforced by the FDA. You must immediately take appropriate steps to correct these violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. These actions may include seizure and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert and future shipments of the product may be subject to detention without physical examination.

We acknowledge receipt of Ms. Wong's fax dated October 2, 2001 in which she provided Seafood Product Safety Specifications for ready-to-eat dried sliced, ready-to-eat dried shredded and ready-to-eat roasted squid. Our review of the Specification Sheets found that your specification for Listeria is not adequate to assure the safety of the fishery product. You need to establish a defined specification for Listeria as you did for Salmonella. A specification is a measurable attribute for which you have established a definitive acceptance value. "Not likely to occur, controlled by SSOP" is not a measurable, defined acceptance value. For your information, FDA has published guidance that sets the acceptable level for *Listeria monocytogenes* in ready-to-eat fishery products as no organisms present. This guidance can be found in FDA's publication, *Fish & Fisheries Products Hazards & Controls Guidance* (http://vm.cfsan.fda.gov/~dms/haccp-2x.html).

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you are doing to correct these violations. You may wish to include in your response, documentation such as copies of product specifications, your firm's HACCP Plan, your foreign processors HACCP Plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda CA 94502-7070. If you have questions regarding any issue in this letter, please contact Mr. Campbell at (510) 337-6861.

Sincerely,

Dawna M. Watson for

Dennis K. Linsley
District Director

Enclosure